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Itemized Response

Reg. To: US Patent Application # 10/662,552

Applicant: Zhang, Xiaohui, 4400 E Broadway blv, Tucson, AZ 85711 Fax: 520-202-3340 ; Phone: 520-202-3333
Title: Methods And System For Bio-Intelligence From Over-The-Counter Pharmaceutical Sales
Mail Date: March 16, 2007
Examiner: Mr. Neal Sereboff, Art Unit 3626

Note of Response:

Reference U is *Goldenberg et al, Early statistical detection of anthrax outbreaks by tracking over-the-counter medication sales,* Proc Natl Acad Sci U S A. 2002 April 16;

Reference V is Armstrong et al, ***Updated Guidelines for Evaluating Public Health Surveillance Systems,*** *CDC* July 27, 2001 / 50(RR13);1-35

Reference [3] is the attached reference by X. Zhang et all, ***A Biointelligence System for Identifying Potential Disease Outbreaks***, IEEE Engineering in Medicine and Biology (EMB), Vol 23, Number 1, 2004.

Response

Action #	Requirement / Question / Advise by The Examiner	Analysis & Response from the Applicant
1	Claim 1 -15 are pending	Response within 3 months
2	Advise to have a patent attorney	Applicant will have a patent attorney soon.
3	Claim 6 and Claim 9 in improper form because of multiple dependent claim should be in the alternative	Corrected Claim 6 and Claim 9 to the alternative form, following the examples in Section 7.45 of MPEP 608.01(n)
4	Appropriate correction is required for verb	Corrected verb 'are' to 'is'
5	Claim 11 partially repeated the language of Claim 10, Appropriate correction is required	Removed the repeated sentence.

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6	Amend the claim, since Claim 15 dependent upon Claim 1, not Claim 12	Removed the sentence that is dependent on Claim 12
7	Copy of '35 U.S.C. 101	Noted
8	'non-statutory subject matter'	The claims 1-15 represent a new useful system, its application demonstrated that it is statutory subject matter according to 35 U.S.C. 101. For elaboration please review the response letter, the attached reference [3] and responses below.
9	(1) Question of 'the results be reproducible' (2) Question on 'Subjective component'	(1) The system and the method in claim 1- 15 have been implemented in a computer system, and said system has been helping public health workers in identifying disease outbreaks. The results are completely reproducible for the given data and conditions. Please see the attached reference publication by X. Zhang et al: A Biointelligence System for Identifying Potential Disease Outbreaks, in IEEE Engineering in Medicine and Biology (EMB), Vol 23, Number 1, 2004. (2) There is no 'subjective component' in this system; it intends to overcome the limits from 'subjective components'. The results are completely based on an analysis of the data and are not dependent on subjective feelings of the analyst. The rules are derived directly from the investigated data itself not from "experience", or other subjective sources. The system automatically takes the historical data to derive the categorized public health status, reference values, decide the state transitions, and make decisions, in a specified place.
10	Implementation of the rule system	(1) The system has been implemented in a computer system,

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		including the rule systems. Several of the included figures are taken from sample implementations. Please see the attached reference publication by X. Zhang et al: A Biointelligence System for Identifying Potential Disease Outbreaks, in IEEE Engineering in Medicine and Biology (EMB), Vol 23, Number 1, 2004. (2) In the patent application, the rule systems are demonstrated in detail (please see paragraph 86 to paragraph 93), step by step, the rule system decides the state transition and inputs/outputs with data referenced in fig. (5) to (8). In fact, the same examples were provided to two different software developers, and they both implemented their application systems independently, one system was published by X. Zhang et al: A Biointelligence System for Identifying Potential Disease Outbreaks, in IEEE Engineering in Medicine and Biology (EMB), Vol 23, Number 1, 2004. The other system is currently in
11	Copy of first paragraph of 35 U.S.C. 112 "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention."	Noted

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12	Question (1) how the invention overcomes existing problems (Background of Invention)	(1) Existing system consider a categorized public health status in a community (such as flu situation) as one of two status: 'normal' or 'outbreak'. Traditionally, analyses are conducted in such binary mode. This is a shortcoming that results from the use of traditional statistical approaches. The usual objective is to try to detect an 'outbreak' (one out of the two status) early. However, the system presented in claim 1- 15 we model for the first time a dynamic change of a categorized public health status in a community by a set of state variables (seven state variables) and the transition of state variables. The seven state variables defined by the applicant are the minimum set to characterize a complete process of a community's public health status. This approach is inherently different from statistical approaches as it integrates dynamic model, rule systems and information technique. •
	(2) lack of method of practicing and working example	(2) The presented system has been described in sufficient detail as a blue print for software engineers to implement as evident in the two independent and successful implementations, which both include the outlined rule systems. Please see the attached reference publication by X. Zhang et al: A Biointelligence System for Identifying Potential Disease Outbreaks, in IEEE Engineering in Medicine and Biology (EMB), Vol 23, Number 1, 2004.

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13	'claim 1 – 15 are rejected, based on a disclosure is not enabling' 'structural implementation'	The system is implemented and already deployed; the implemented system has been running since 2003 and has successfully aided a Public Health department in the cognition of several otherwise unknown disease outbreak events. Please see the attached reference publication by X. Zhang et al: A Biointelligence System for Identifying Potential Disease Outbreaks, in IEEE Engineering in Medicine and Biology (EMB), Vol 23, Number 1, 2004. Examples of implementation are provided in the attached publication by X. Zhang et al: A Biointelligence System for Identifying Potential Disease Outbreaks, in IEEE Engineering in Medicine and Biology (EMB), Vol 23, Number 1, 2004.
14	Claim 1-15 are rejected, as failing to comply with enablement requirement. working example or instruction	Working example is provided in the attached publication by X. Zhang et al: A Biointelligence System for Identifying Potential Disease Outbreaks, in IEEE Engineering in Medicine and Biology (EMB), Vol 23, Number 1, 2004.
15	quotation of the second paragraph of 35 U.S.C. 112: "The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention."	Noted Please see response to Action 16.

Action #	Requirement / Question / Advise by The Examiner	Analysis & Response from the Applicant
16	Need to define the invention required by 15	Two of obvious inventions are identified as examples: It is the first time (an invention), that a dynamic change of a categorized public health status in a community is modeled by a set of state variables (seven variables) and the transition of state variable in a dynamic model. The seven state variables defined by the applicant are the minimum set to characterize a complete process of a community's categorized public health status. It is the first time, which in dynamic modeling in state space approach, the state transition matrix is systematically defined by a combination of numerical functions and rule base and knowledge management.
17	Language and format The claim must be in one sentence form only	Modified format.
18	Use of 'the' and 'a' in Claim 1	Corrected 'the rule system' to 'a rule system' in Claim 1
19	Use of 'the' and 'a' in Claim 1	Corrected
20	Use of 'the apparatus'	Corrected in Claim 1
21	Use of 'the' baseline	Corrected to 'a'
22	Claim 3 -5 failing to point out and distinctly claim the invention Claim 3 -5 dependent upon Claim 2	Modified Claim 3 – 5.
23	Claim 10 failing to point out and distinctly claim the invention	Mended the sentence, as

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	Question: what is being mapped	The structural components are mapped incorporating their confidence levels.
24	quotation of the paragraph of 35 U.S.C. 102: "A person shall be entitled to a patent unless – (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States."	Noted.
25	Claim 1 – 5, 7, 10-15 are rejected, because of Goldenberg et al "Early statistical detection of anthrax outbreaks by tracking over-the-counter medication sales" , reference U	Please see the response to Action 26.
26	As per claim 1, The first paragraph: 'Goldenberg teaches the system for detecting an unusual public health status and for modeling the change of categorized public health status from OTC pharmaceutical data'	In reference U, Goldenberg, as all other public health workers, does not define 'public health status' as a set of state variables, does not model 'the change of categorized public health status', there is no word of 'public health status' appeared in Reference U. Goldenberg tries to use OTC data to detect an outbreak only (distinguish an 'outbreak' from 'normal'), he doe not mention how to model the detection in the space of state variables as described in Claim 1. Goldenberg's approach is the traditional statistical approach with a signal detection for Normal or Attack (outbreak); while the system presented in claim 1- 15 describes a complete process for a categorized public health status in a community.

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		Conclusion: Claim 1 is different from the one in the reference.
	The second paragraph: A measurement scheme defined by a set of variables and calculation of categorized daily OTC sale data in a specified geographical scale (page 2, Tracking Grocery Data section, paragraph 1 where geographical scale is noted by address)	Quotation of Tracking Grocery Data section, paragraph 1 (of reference U): **"Tracking Grocery Data** Grocery and OTC medication sales have three main advantages for the detection of an outbreak: First, these datasets are typically very large and rich, including information on each purchased item and in many cases include customer information(e.g., address). They are also available on a more frequent scale, such as daily and even hourly basis, and do not include delays in reporting as compared with medical and public health sources which are typically collected weekly or even less frequently, and might contain delays. Second, the outbreak footprint would probably exist in these data earlier than in medical or public health data, because of self treatment that people usually pursue before seeking medical assistance. Third, although grocery and OTC sales do not measure illness directly, we might infer specific symptoms experienced by purchasers at a relatively early stage of the onset of the disease." Analysis: In this paragraph, Goldenberg summarized the advantages of using OTC data. We agree with his analysis of the benefits, which is why we are working with the same data source. No specific method is presented. Goldenberg mentioned the use of customer information (e.g. address). Immediately in the following paragraph, Goldenberg pointed out 'the main problem using grocery and OTC medication sales is their noise nature'. In Claim 1 – 15, no a customer address is required or used. In section of Summary of Invention, a study area or a geographical level is defined by a pharmacy store service area, a zip code area, a city, a county, and a statewide area; while the application of the claimed system and method is the same.

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		The system of variables and calculations demonstrated elsewhere in Goldenberg is of a mathematically very different nature with all the discussed shortcomings of statistics based approaches to the "noise" in data. Conclusion: The claims are different from the one in the reference.
	The third paragraph An algorithm for unusual public health status (or event) detection incorporating seasonally varying reference lines (see page 2, Tracking Grocery Data, paragraph 5), and calculating three structural components from the input data: • a daily deviation from the reference line (see Figure 3), • an n-days-cumulated-deviation, and (see Figure 3) • the change of the daily deviations in that area, (see Figure 3)	Quotation of reference U, page 2, Tracking Grocery Data, paragraph 5: " Our proposed detection system consists of several layers (A.G., G.S., and R.A.C., unpublished results). The first layer preprocesses the data by accounting for store level sales. The second layer puts the preprocessed data through a denoising filter. We use the discrete cosine transform (10, 11), which decomposes the series into cosine waves, and our filter retains only those that have a large magnitude. We chose the number of retained cosine waves to capture the main features of the series but also to avoid overfitting (A.G., G.S., and R.A.C., unpublished results)." Analysis: In reference U, (page 2, Tracking Grocery Data, paragraph 5) Goldenberg uses their 'unpublished results', and a wavelet transform, which is totally different from the approach in the Claim 1. In reference U, Figure 3, Goldenberg compares the sales data with the threshold which 'is in fact three standard deviations', as Goldenberg writes in Page 3, the second paragraph (above Figure 3), as a typical statistic approach. Goldenberg does not mention an n-days-cumulated-deviation in Figure 3, not in his paper either; Goldenberg does not mention the change of the daily deviation in

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		Figure 3, not his paper either. Conclusion: the claims are different from the one in the reference.
	The fourth paragraph A dynamic system model describing the categorized public health status by a set of state variables, and the change of the health status by the state transition, the input sets, the output sets, and the rule systems that govern them (see Page 3 paragraph 1)	Copy of Page 3, paragraph 1 of Reference U: " First, we decompose the denoised series into several ''resolutions'' by using a discrete (redundant) wavelet transform (ref. 12; cf. the continuous version of wavelets in ref. 13). Each resolution describes a different frequency of the series,.but, unlike other transforms (e.g., the cosine and Fourier transform), it retains information on the *time* that each frequency is present. The resulting series for each resolution are more regular, and thus we use a simple autoregressive model (where the sales at time *t* are taken to be a weighted average of previous sales) for predicting each resolution separately. We then add the predictions to create the forecast of the next day sales. Fig. 2 shows the decomposition of the (preprocessed and denoised) series into five resolutions. For each resolution, we use an autoregressive model for forecasting the next point. Finally, we add the forecasts to obtain the next point in the series, i.e., Fig. 2 also includes the combined forecast of the next day (denoised) sales." Analysis: In Page 3, paragraph 1 of Reference U, Goldenberg describes 'a wavelet transform' and 'a simple autoregressive model'. His transform is a mathematical treatment/model of the problem which has no physical meaning nor describes a public health concept or content; his autoregressive model is for 'forecast of the next day sales'. The proposed patent matches each state variable with a public health concept/content, which is very unique to the proposed patent and not possible with "normal" modeling approaches. Goldenberg does not mention a model with a set of state variables, and does not model a change of the public health status by the state transition either.

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		Conclusion: the claims are different from the one in the reference.
	The fifth paragraph The rule system determines the state transitions for modeling the dynamic change of public health status through the analysis of information derived from OTC pharmaceutical sales in that area (see page 3, paragraph 1)	Copy of Page 3, paragraph 1 of Reference U: " First, we decompose the denoised series into several ''resolutions'' by using a discrete (redundant) wavelet transform (ref. 12; cf. the continuous version of wavelets in ref. 13). Each resolution describes a different frequency of the series, but, unlike other transforms (e.g., the cosine and Fourier transform), it retains information on the *time* that each frequency is present. The resulting series for each resolution are more regular, and thus we use a simple autoregressive model (where the sales at time *t* are taken to be a weighted average of previous sales) for predicting each resolution separately. We then add the predictions to create the forecast of the next day sales. Fig. 2 shows the decomposition of the (preprocessed and denoised) series into five resolutions. For each resolution, we use an autoregressive model for forecasting the next point. Finally, we add the forecasts to obtain the next point in the series, i.e., Fig. 2 also includes the combined forecast of the next day (denoised) sales." Analysis: In Page 3, paragraph 1 of Reference U, Goldenberg describes 'a wavelet transform' and 'a simple autoregressive model'. His transform is a mathematical treatment/model of the problem which has no physical meaning nor describes a public health concept or content; his autoregressive model is for 'forecast of the next day sales'. The proposed patent matches each state variable with a public health concept/content. Goldenberg's autoregressive model attempts to create the 'forecast of the next day sales'. Goldenberg does not mention the state transition, and the method he used here (simple autoregressive model) is a traditional statistical method, it is not a rule system, it is not for modeling the dynamic change of public health status either.

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		Conclusion: the claims are different from the one in the reference.
	The sixth paragraph A rule system combines the structural components incorporating the confidence supporting sets as the input variables (see page 3, paragraph 2 where the confidence arises by defining the input boundaries)	Quotation of paragraph 2 in page 3 of reference U: "The final layer of the detection system includes the computation of an upper threshold for the next day forecasts. This threshold is based on the forecast made in the previous step, plus a margin of error. When the actual next day sales become available, they are compared with the threshold. If they exceed the threshold, the system flags an alarm, indicating that the new daily sales are higher than expected. The threshold is based on the distribution of the differences between the forecasts and the real sales, and is in fact three standard deviations of the differences above the denoised series. This last step is based on a methodology used in statistical quality control, called control charts, where a process is monitored by using a chart that flags when a change occurs, while taking into account natural variation of the series (14). Fig. 3 illustrates the threshold for the cough OTC medication data. The threshold follows the series, creating a ''security band,'' which, if exceeded, is an indication that the sales are higher than expected. For example, sales for 8_7_00 are higher than the prediction. They do not exceedthe threshold, however, and thus we do not take them to indicate an abnormal increase in sales." Analysis: In the Claim 1, three structured components are defined. The claim further describes a rule system combining the three components with confidence supporting sets (where the confidence supporting sets are defined by equation 7 - 9 in later section) as the input variables. The input variables are different from input data which is raw sale data. Also note, that confidence supporting set in the proposed method is not equivalent to 'three standard deviation'. In reference U, Goldenberg does not have those three components, no confidence supporting sets of those three components either. In reference U, page 3, paragraph 2, Goldenberg uses a threshold,

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		'this threshold is based on the forecast…, plus a margin of error', then to compare with the daily sales. (another example of analyst subjectivity in analysis, which the proposed method does not require) Conclusion: the claims are different from the one in the reference.
	The seventh paragraph A rule system maps the state history to the output variables (see Figure 5 where state history is determined by the amount of antibiotic being purchases).	Analysis: In reference U, Goldenberg has to create a simulation to evaluate their method, 'we devised a statistical simulation approach' (page 3, section of Evaluating the detection system, the first paragraph). And Goldenberg further assumes a medication sales pattern 'is a three-spike linearly increasing pattern', 'steadily over the first 3 days' (this is another example of analyst subjectivity). Goldenberg then 'measures the spike detection ratio (SDR, Goldenberg et al unpublished results)' (see page 3, paragraph 2 in reference U). Figure 5 shows the SDR. In Claim 1, this sentence describes a rule system that maps a set of state variables and their transition history into output variables; and the mapping is further defined by equation 12 in later section. Here the value of an output variable, as defined by equation 15, is the combination of three elements, the likelihood index of abnormality, the trend indicator and the potential impact index. Goldenberg's output is simply a ratio of spike detection. Goldenberg does not mention the state variables, no history of a set of state variables, no likelihood index, no trend indicator, no

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		potential impact index at all. Conclusion: The claims are different from the one in the reference.
27	As per Claim2, Goldenberg teaches the system wherein said measurement scheme includes the calculation of monthly (or weekly, or daily, or seasonally) averaged daily sales for the categorized OTC medicines as the base line, from the data in the past at the same place, which is one data set (base line) for supporting the rule system (see Figure 1).	Analysis: Figure 1 in Reference U, Goldenberg shows the OTC data noisy nature by plotting the raw data and the de-noising data. In reference U, Goldenberg does not mention the weekly or monthly averaged daily sales. The word 'weekly' are used twice total by Goldenberg in his paper: (1) one is about the data in ' medical and public health sources which are typically collected weekly or even less frequently,' (page 2 last paragraph), (2) the other is 'weekly effect showing higher sales during weekends'. No word 'monthly' ever used in Reference U by Goldenberg. Therefore, Goldenberg does not teach the system as described in claim 1 or 2. Conclusion: The claim is different from the one in the reference.
28	As per claim 3, Goldenberg teaches the system wherein said measurement scheme includes the calculation of the deviation of daily sales in the current-month from the base line, and it is measured in change of percentage at the same place, which is another data set (the first structural component) for supporting the rule	Analysis: In reference U, Figure 3, Goldenberg compares the sales data with the threshold which 'is in fact three standard deviations', as Goldenberg writes in Page 3, the second paragraph (above Figure 3), as a typical statistic approach. Goldenberg compares the raw sale data to their forecasts. His approach is different from the method defined in Claim 3. which

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	system (see figure 3).	explicitly defined the baseline is derived directly from the historical data in that month at the same place, no forecast model is assumed, thus no subjectivity in model choice is necessary in the proposed patent. Conclusion: The claim is different from the one in the reference.
29	As per claim 4, Goldenberg further teaches the system wherein said measurement scheme includes the calculation of the n-days-cumulated-deviation, which is another data set (the second structural component) for supporting the rule system (see figure 3).	Analysis: In reference U, Figure 3, Goldenberg compares the sales data with the threshold which 'is in fact three standard deviations', as Goldenberg writes in Page 3, the second paragraph (above Figure 3), as a typical statistic approach. Goldenberg does not mention n-day-cumulated-deviation in his paper. No word 'cumulated' or the concept of 'cumulated-deviation' is used in his paper. Conclusion: The claim is different from the one in the reference.
30	As per claim 5, Goldenberg further teaches the system wherein said measurement scheme includes the calculation of the daily change of the deviation, which is another data set (the third structural component) for supporting the rule system (see figure 3).	In reference U, Figure 3, Goldenberg compares the sales data with the threshold which 'is in fact three standard deviations', as Goldenberg writes in Page 3, the second paragraph (above Figure 3), as a typical statistic approach. Goldenberg does not mention 'change of the deviation' at all. The word 'deviation' is used only once in his paper, where he describes his approach using in fact three standard deviations. In Claim 5, the calculation of the daily change of the deviation is

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		defined by equation 6. Conclusion: The claim is different from the one in the reference.
31	As per claim 7, Goldenberg further teaches the system wherein said dynamic model of the categorized public health status is defined by the system with a set of state variables and state transitions over the time dimension at a specified place, with which state transitions model the change of the categorized public health status (see page 2, Tracking Grocery Data section, paragraph 1 where the state variables and public health are tracked through antibiotic sales).	Quotation of Tracking Grocery Data section, paragraph 1 (of reference U): "**Tracking Grocery Data** Grocery and OTC medication sales have three main advantages for the detection of an outbreak: First, these datasets are typically very large and rich, including information on each purchased item and in many cases include customer information(e.g., address). They are also available on a more frequent scale, such as daily and even hourly basis, and do not include delays in reporting as compared with medical and public health sources which are typically collected weekly or even less frequently, and might contain delays. Second, the outbreak footprint would probably exist in these data earlier than in medical or public health data, because of self treatment that people usually pursue before seeking medical assistance. Third, although grocery and OTC sales do not measure illness directly, we might infer specific symptoms experienced by purchasers at a relatively early stage of the onset of the disease." Analysis: Goldenberg does not define the public health status by state variables, does not define the dynamic model that governs the stat transition which describes the dynamic process of public health status. Conclusion: The claim is different from the one in the reference.
32	As per claim 10, Goldenberg further teaches the system	Quotation of page 1 paragraph 3 in reference U: "We begin in the next section by providing background and a characterization of an outbreak of a bioagent, focusing on anthrax. Then we describe traditional data collected

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		from medical and public health sources and their ability to detect attacks in a timely fashion, before turning to grocery data and the detection system that we developed. We also introduce a method for evaluating the detection system in the absence of a bioagent footprint in the data, and for tuning the system to the input data. We end with some observations on the usefulness of our approach."
	(1) wherein said input sets are the supporting sets for the state transition rule systems (see page 1 paragraph 3);	Analysis: Goldenberg does not mention state variables, no state transition, no supporting sets for the state transition either. Goldenberg mentioned 'input data'. However, Goldenberg's 'input data' is the simulated data, created with his assumptions including the time pattern and spike rising pattern. (see page 4, the second paragraph). In Claim 10, there are no assumptions for input sets. However, the applicant mended the sentence in Claim 10 to further clarify what is being mapped, please see the response to Action 23: "the structural components are mapped incorporating their confidence levels." Conclusion: The claim is different from the one in the reference.
	(2) it is mapped from the structural components incorporating the confidence levels (see figure 2 and page 3 paragraph 2 where statistical quality control creates	Analysis and response of (2) : Fig. 2 in reference U has two diagrams, and they are the results of Wavelet Transform for prediction. Goldenberg compares the sales data with the threshold which 'is in fact three standard deviations',

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	confidence levels).	as Goldenberg writes in Page 3, paragraph 2 (above Figure 3), as a typical statistic approach, not in state pace, no rule system either. In Claim 10, the approach is defined in state space, and claim 10 further describes the input sets are supporting sets for state transition rule system, and the input sets are function of the confidence level for each structural component. Equation 11 defines the mathematical relation of them. Conclusion: The claim is different from the one in the reference.
33	(1) As per claim 11, Goldenberg further teaches the system wherein said input sets are the supporting sets for the state transition rule systems (see page 1 paragraph 3); (2) it is mapped from the structural components incorporating the confidence	Analysis of (1) : Quotation of page 1 paragraph 3 in reference U: "We begin in the next section by providing background and a characterization of an outbreak of a bioagent, focusing on anthrax. Then we describe traditional data collected from medical and public health sources and their ability to detect attacks in a timely fashion, before turning to grocery data and the detection system that we developed. We also introduce a method for evaluating the detection system in the absence of a bioagent footprint in the data, and for tuning the system to the input data. We end with some observations on the usefulness of our approach." Response: Goldenberg does not mention input sets, not state transition either; not in page 1 paragraph 3, not in his paper at all. Conclusion of (1): The claim is different from the one in the reference. Analysis of (2) In reference U, Figure 3, Goldenberg compares the sales data

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	levels (see figure 3 and page 3 paragraph 2 where statistical quality control creates confidence levels), (3) where the confidence levels are derived from the historical data sets (see page 3 paragraph 2 where the historical data set are the natural variation), (4) and the confidence supporting sets are found from the cumulated distribution functions with the specified confidence levels (see figure 3 and page 3 paragraph 2 where the specified confidence level is the security band).	with the threshold which 'is in fact three standard deviations', as Goldenberg writes in Page 3, paragraph 2 (above Figure 3), as a typical statistic approach. Response to (2) : Goldenberg does not mention the structural components as described in Claim 11, he does not mention how to incorporate their confidence level either. Analysis of (3) and (4): See response to action 26 for Quotation of paragraph 2 in page 3 of reference U. Analysis: Goldenberg has a totally different approach. He computes the forecasts, compares the raw sale data to the forecasts plus a margin of error. The historical data set are not the natural variation, although the historical data sets (and the structural components) contain the natural variation. Goldenberg tries to use wavelet transform to model the natural variation. Goldenberg's security band is "in fact three standard deviations of the differences above the denoised series" as he wrote. In contrast, in Claim 11, the confidence supporting sets are functions (defined by equation 7, 8 and 9) which are a significant improvement and new invention, eliminating the analyst's subjectivity in choice of thresholds, and assumptions commonly found in his simulated input data. Response to (3) and (4): The applicant can not find how Goldenberg teaches the same

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		system.
34	As per claim 12, Goldenberg further teaches the system wherein said output sets are a set of vectors (see page 3 paragraph 1 where the vectors are resolutions), each with three values: likelihood, trend indicator, and impact indicator, where the output sets are mapped from the state history at the study place (see figure 2 where the values are related to their normalized counts).	Quotation of page 3 paragraph 1 in reference U: "First, we decompose the denoised series into several ''resolutions'' by using a discrete (redundant) wavelet transform (ref. 12; cf. the continuous version of wavelets in ref. 13). Each resolution describes a different frequency of the series, but, unlike other transforms (e.g., the cosine and Fourier transform), it retains information on the *time* that each frequency is present. The resulting series for each resolution are more regular, and thus we use a simple autoregressive model (where the sales at time *t* aretaken to be a weighted average of previous sales) for predictingeach resolution separately. We then add the predictions to create the forecast of the next day sales. Fig. 2 shows the decomposition of the (preprocessed and denoised) series into five resolutions. For each resolution, we use an autoregressive model for forecasting the next point. Finally, we add the forecasts to obtain the next point in the series, i.e., Fig. 2 also includes the combined forecast of the next day (denoised) sales." Analysis: Goldenberg uses wavelet transformations (not state variables) and gets several "resolutions". He does not say what wavelet function is used, and the 'resolution' is the results of transform in frequency, it has no physical meaning and no public health contents either. In the claims, including claim 12, in contrast to the reference U, state variables and a dynamic model of state transitions are used; Claim 12 describes how the history of the state variables are mapped into the output sets, and each output variable contains 3 elements, with public health meaning: likelihood, trend indicator, and impact indicator, which Goldenberg does not mention any of them (not in Fig 2 either) nor are any equivalent measures offered.

Action #	Requirement / Question / Advise by The Examiner	Analysis & Response from the Applicant
		Conclusion: The claim is different from the one in the reference.
35	As per claim 13, Goldenberg further teaches the system wherein said rule system that governs the state transitions is the system with sets of logical rules, which evaluate both the logical and numerical functions to determine the system states (see page 2 paragraph 10 where the methodology encompasses two-stage prediction system with both logical and numerical functions).	Quotation of page 2 paragraph 10 in reference U: " The third layer of the system forecasts the next day sales given all of the previous sales. Although the data are now denoised, simple time-series models (e.g., autoregressive moving average models) do not perform well because of the non-stationarity of the series, i.e., the changes in their behavior over time cannot be characterized by simple time-series models. Instead, we use a two-stage prediction method suitable for non-stationary data that can be easily automated and yields more accurate predictions." Analysis: Goldenberg does not say what his two-stage prediction is; he does not mention the state variables, not state transitions either in his paper. And no rule system governs the state transition in his paper. Therefore, the claim is different from the one in the reference.
36	As per claim 14, Goldenberg further teaches the system wherein said rule system that processes the structural components is a rule system with both logical and numerical functions mapping the structural components to supporting sets (see figure 2).	Analysis: Goldenberg uses wavelet transform, not the state variables as in the claim 1- 15. In the proposed patent, the rule system processes state variables, with both logical and numerical functions. Figure 2 shows his wavelet transform results. There is no word of 'rule' or word of 'logic' is used in reference U. Therefore, the claim is different from the one in the reference.
37	As per claim 15, Goldenberg further	Analysis: Goldenberg uses wavelet transform and auto-regression

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	teaches the system wherein said rule system that maps the state history to the output variables is a rule system with both logical and numerical functions mapping the state variables to the output variables which are described in Claim 12 (see figure 2 where the output variables are the prediction).	to forecast the sales; while the claims use state variable and dynamic model of state transitions, a rule system maps the state history into the output variables, each output variable has 3 elements as describes in Claim 12. Goldenberg does not use state variables, no rule system, nor any of those three elements. See response to Action 34. Therefore, the claim is different from the one in the reference.
38	Quotation of 35. U.S.C. 103(a)	Noted.
39	Claim 8 is rejected because of reference U and reference V on the attached.	See response to action 40.
40	(1) As per claim 8, Goldenberg teaches the apparatus of claim 7…. Armstrong teaches the apparatus, (see page 7 Measure paragraph 2)	See response to action 31. Goldenberg does not define the public health status by state variables, does not define the dynamic model that governs the state transitions which describes the dynamic process of public health status. No word of 'state' or 'dynamic model' is used in Reference U. Thus, the applicant can not agree 'Goldenberg teaches the apparatus of claim 7'.
40	(2) Armstrong teaches the apparatus, (see page 7 Measure paragraph 2)	Quotation of page 7 Measure paragraph 2 in reference V by Armstrong et al: "**Measures.** Parameters for measuring the importance of a health-related event---and therefore the public health surveillance system with which it is monitored---can include (7) • indices of frequency (e.g., the total number of cases and/or deaths; incidence rates, prevalence, and/or mortality rates); and summary measures of population health status (e.g., quality-adjusted life years [QALYS]); • indices of severity (e.g., bed-disability days, case-fatality ratio, and hospitalization rates and/or disability rates);

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		• disparities or inequities associated with the health-related event; • costs associated with the health-related event; • preventability (*10*); • potential clinical course in the absence of an intervention (e.g., vaccinations) (*11,12*); and • public interest. Analysis: The content described in the application Claim 1- 15 is 'a dynamic process of categorized public health status in a community (such as flu, or gastrointestinal diseases) at a place in a specified time, the process changes in hourly and daily, it is totally different from the above reference which measure by years, disability, and cost etc. Response: Applicant can not see how reference V defined the dynamic process of categorized public health status in a community with set of state variables, as healthy status, critical status, starting-unusual status, upward-trend-unusual status, peak-unusual status, downward-trend status, and ending-unusual status. The cited reference is delineating the administrative approach to public health status, not introducing a model by which the health status of a population can be described automatically and consistently. The state variables used in the proposed method and the health status indicators used in the cited sources are of a very different nature. One key difference is that the cited indicators do not relate to the field of early detection of public health events.
40	(3) Armstrong page 3, Summary paragraph 1	Quotation of reference V, page 3, Summary paragraph 1

Action #	Requirement / Question / Advise by The Examiner	Analysis & Response from the Applicant
		Summary *"The purpose of evaluating public health surveillance systems is to ensure that problems of public health importance are being monitored efficiently and effectively. CDC's* Guidelines for Evaluating Surveillance Systems *are being updated to address the need for a) the integration of surveillance and health information systems, b) the establishment of data standards, c) the electronic exchange of health data, and d) changes in the objectives of public health surveillance to facilitate the response of public health to emerging health threats (e.g., new diseases). This report provides updated guidelines for evaluating surveillance systems based on CDC's* Framework for Program Evaluation in Public Health, *research and discussion of concerns related to public health surveillance systems, and comments received from the public health community. The guidelines in this report describe many tasks and related activities that can be applied to public health surveillance systems. "* Response: The applicant fully supports the above Summary, and systematically developed a new method (as detailed in claims 1-15). This method has been implemented in computer systems to improve the public health surveillance in real world. While the success of that implementation system can be assessed through the guidelines proposed in the cited source, the cited source does not disclose or cover the methods introduced by the application in any manner.

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